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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,969	12/14/2001	Richard A. Pittner	0401-UTL-0	7314
28381	7590	03/03/2004	EXAMINER	
ARNOLD & PORTER LLP ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,969	Applicant(s) PITTNER ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/26/2003 & 9/30/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8 and 33-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8 and 33-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/26/03 & 1/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

The Request filed on September 26, 2003 for Continued Examination (RCE) under 37 CFR 1.114 of Application 10/016, 969 is granted. An action on the RCE follows.

Applicants' Amendment and Claims

Applicants' amendment filed on September 26, 2003 has been entered in full. Claims 1, 8, 33 have been amended. Claims 2-7 and 9-23 have been canceled. New claims 34-51 have been added. Applicants' amendment filed on September 30, 2003 has also been entered in full. Claims 33, 38-42, 45-48, and 51 have been amended. New claims 52-54 have been added. Claims 1, 8, and 33-54 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Information Disclosure Statement

The information disclosure statement filed on September 26, 2003, and January 12, 2004 has been considered in full and a signed copy of the Form 1449 is enclosed.

It is noted that applicants have cited a number of references in a letter submitted on September 22, 2003. However, a PTO-1449 form has not been submitted to the office. It is advised that a PTO-1449 form be submitted in order for the cited references to be officially considered.

Withdrawn Rejections

The rejection of claims 6, 7, 11, 12, 31, and 32 under 35 U.S.C. §112, 1st paragraph for New Matter, as set forth at pages 2-3 of the previous Office Action (Paper No. 16, June 18, 2003), has been made moot by Applicants' cancellation of the claims.

The rejection of claims 4, 5, 9, 10, 23, and 29 under 35 U.S.C. §103(a), as set forth at pages 3-5 of the previous Office Action (Paper No. 16, June 18, 2003), has been made moot by Applicants' cancellation of the claims.

Claim Rejections Under 35 U. S. C. § 102 (b)

(i) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(ii) Claims 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (*The Endocrine Society 75th Annual Meeting Program & Abstract*, page 180, Abstract 520B, 1993).

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Okada et al. teach a method of reducing high fat diet intake comprising peripherally administering PYY to male Sprague-Dawley rats at the doses of 1, 10, 20, and 40 nmol (equivalent to about 4.3, 43, 86, and 172 μ g, respectively; molecular weight of PYY=4310). Assuming the body weight of the rats are 200g, the doses of PYY taught by Okada et al. also fall reasonably within the dose range of PYY recited by the instant claims. Okada et al. further teach that PYY is a satiety factor for fat meal. Since reducing food intake is necessarily linked to reduction of appetite, the reference of Okada et al. meets the limitations of claims 45-47.

Claim Rejections Under 35 U. S. C. § 103 (a)

In view of Applicants' argument, amendment to the claims, and for the purpose of clarity, the 103(a) rejection set forth at pages 2-5 of previous office action (Paper No. 10, November 15, 2002) has been modified and new rejections are set forth below.

(i) Claims 1, 8, 33-44, 48-50, and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaisse-Lagae et al. (*Experientia* 33:915-917, 1977) in view of Okada et al. (*The Endocrine Society 75th Annual Meeting Program & Abstract*, page 180, Abstract 520B, 1993), Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992), and Ueno et al. (*Gastroenterology*, 117:1427-1432, 1999).

Malaisse-Lagae et al. teach a method of treating obesity comprising administering to obese mice a therapeutic effective amount of pancreatic polypeptide (See, e.g.,

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Abstract). The obese mice were fed with a standard pellet diet (left column of page 916), which is non-high fat food. Peripherally administration of 5 $\mu\text{g/kg}$ body weight per dose or 50 $\mu\text{g/kg}$ body weight per dose (two daily injections) reduced food intake and suppressed body weight (page 916).

Malaisse-Lagae et al. fail to teach the use of peptide YY (PYY)/PYY agonist.

Okada et al. teach a method of reducing high fat diet intake comprising peripherally administering PYY to male Sprague-Dawley rats at the doses of 1, 10, 20, and 40 nmol (equivalent to about 4.3, 43, 86, and 172 μg , respectively; molecular weight of PYY=4310). The rats were fed high fat food which contains 56% of its calory as fat. Okada et al. also teach PYY is more potent than NPY in suppressing high fat food intake. Okada et al. further teach that PYY is a satiety factor for fat meal.

Yoshinaga et al. teach inhibition of pancreatic exocrine and gastric acid output by peptide YY and a PYY agonist, PYY3-36 (see, e.g., Abstract) that selectively binds to Y2 or Y5 receptor, which is known in the art (as evidenced by, e.g., Grandt et al., Pancreas 13: 80-8, 1996) and as acknowledged in the specification (lines 12-13 of page 2).

Ueno et al. teach decreased food intake and body weight in pancreatic polypeptide-overexpressing mice and that physiological doses of PP inhibit pancreatic exocrine secretion (1st paragraph of right column of page 1427).

Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the PYY and a PYY agonist, e.g., PYY3-36, in the method of treating obesity and reducing food intake as taught by Malaisse-Lagae et al. with a reasonable expectation of success. Reducing caloric efficiency and nutrient availability are biological outcomes of the method of treatment for obesity, reducing food intake (high and low fat food), and suppressing body weight with PYY or its agonist, PYY 3-36. Also, reducing food intake is necessarily linked to reduction of appetite. One would have been motivated to do so because both PP and PYY decrease food intake, both belong to the pancreatic polypeptide family, and both function as an inhibitor of pancreatic exocrine, as taught by the cited art.

(ii) Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malaisse-Lagae et al. in view of Okada et al., Yoshinaga et al., and Ueno et al., as applied to claims 1, 8, 33-44, 48-50, and 52-54, and further in view of Naslund et al. (Int. J. Obes. Relat. Metab. Disord. 23:304-311, 1999).

The combined teachings of Malaisse-Lagae et al., Okada et al., Yoshinaga et al., and Ueno et al. teach a method of reducing caloric efficiency, food intake, or appetite comprising administering to a subject an effective amount of PYY or a PYY agonist, as applied to claims 1, 8, 33-44, 48-50, and 52-54. None of the cited references teach

administering GLP-1, an exendin, an amylin or their agonists in combination with PYY or a PYY agonist.

Naslund et al. teach that intravenous infusion of GLP-1 suppress energy intake and appetite in obese men (Abstract).

Therefore, It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method taught by Malaisse-Lagae et al., Okada et al., Yoshinaga et al., and Ueno et al. and to administer GLP-1 in combination with PYY or a PYY agonist with a reasonable expectation of success. One would have been motivated to do so because GLP-1 has been clearly shown to decrease feelings of hunger and reduces energy intake by Naslund et al. and the combination of GLP-1 with PYY/PYY agonist is expected to be successful since they have the same effect.

Conclusion

No claims are allowed.

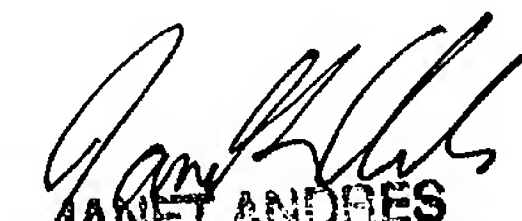
Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875.

The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Ruixiang Li
Examiner
February 26, 2004



JANET ANDRES
PATENT EXAMINER